

REMARKS

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for indicating that claim 17 contains allowable subject matter.

Preliminary Matters

Applicant's representative contacted the Examiner by phone on May 29, 2005 to confirm that the Office Action Summary page included typographical errors. The rejected claims should have been claims 1-16 and 18-24, while the objected claim should have been claim 17. This response is based on the corrected claim numbers.

Disposition of Claims

Claims 1-24 are pending in this application. Claims 1, 8, and 18 are independent. The remaining claims depend, directly or indirectly, from these claims.

Claim 18 is amended in this response to clarify the present invention recited. This amendment clarifies that the activation of the apparatus *causes a rapid temperature change in a suspected area of infection*. No new matter is added by way of this amendment, support for which may be found at least in Paragraphs 15 and 21-24 of the specification as filed.

Rejection under 35 U.S.C § 112

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This claim has been amended. Accordingly, withdrawal of this rejection is

respectfully requested.

Rejections under 35 U.S.C § 102

Claims 1-11, 16, and 18-24 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent Application No. 2002/0143373, by Courtnage et al. (“Courtnage”). Claim 18 has been amended in this reply to clarify the present invention recited. To the extent that this rejection may still apply to the amended claims, the rejection is respectfully traversed.

Courtnage discloses a multi-layered therapeutic device comprising photon-emitting diodes alone or in combination with transcutaneous electrical stimulation to stimulate natural healing processes (Paragraph 12). Courtnage also cites to a number of studies in which light therapy and/or electrotherapy results in the formation of new blood vessels, stimulates DNA and RNA synthesis, increases protein synthesis, accelerates cellular metabolism, increases revascularization, increases cell growth, and otherwise *enhances normal metabolic pathways* (Paragraphs 6-10).

Heating is disclosed by Courtnage only with respect to forming the resin of a housing for the disclosed device (Paragraphs 13 and 15), and with respect to whether a *housing* surrounding the LEDs and/or electrical stimulators is formed of an insulating material to enhance heat concentration or a heat conductive material to dissipate heat (Paragraph 17). Courtnage neither discloses nor suggests any type of cooling.

Any heating that may occur during use of the Courtnage device will occur as a by-product of the use of light sources. The light sources utilized by Courtnage emit a relatively small amount of heat as a by-product of their light production. This is

evidenced by Courtnage's use of LEDs (Light-Emitting Diodes – Paragraph 12). LEDs have become increasingly popular for their efficiency, as evidenced by the fact that they produce very little heat compared to traditional incandescent light sources. Accordingly, any heat transfer to a living organism by the Courtnage device will be very gradual due to the relatively low heat emission of the disclosed diodes. Such low-level heating, possibly resulting in a gradual small increase in localized tissue temperature, is consistent with Courtnage's stated goal of stimulating natural physiological healing processes.

In contrast to Courtnage, the method of independent claim 1 requires a *rapid* temperature change. Rapid temperature changes are believed by the Applicant to, among other things, decrease a pathogen's rate of replication (versus Courtnage's increased cell growth and metabolism), denature proteins (versus Courtnage's increased protein synthesis), constrict blood vessels (versus Courtnage's increased circulation), and otherwise inhibit certain natural pathways and physiological responses, in contrast to Courtnage's facilitation of such pathways and responses. (Comparing Paragraphs 20-21 of the instant application, with Paragraphs 7-10, 16, and 57 of Courtnage, including Courtnage's reference to and incorporation of numerous patents relating to light therapy whereby specific wavelengths are believed to stimulate cell growth and replication, growth-factor secretions, and similar natural processes.)

Many of the physiological mechanisms believed to underlie the efficacy of embodiments of the instant invention rely to some extent on a "shock" to various metabolic systems, achieved by the *rapidity* of localized temperature changes, as well as the extent of such changes. Such an effect contrasts sharply with the facilitation of natural metabolic processes according to Courtnage.

Claim 1 also requires the *assessing* of a suspected area *for occurrence of infection* after causing and then discontinuing a rapid temperature change. Courtnage discloses only EMG and thermal sensors and neither discloses nor suggests that such sensors may be used to assess for occurrence of infection.

Furthermore, Courtnage neither discloses nor suggests the use of a *predetermined* temperature to determine how long to continue, or when to discontinue, a rapid temperature change, as required by claims 2-3. As previously discussed, no rapid temperature change is disclosed or suggested by Courtnage. Furthermore, Courtnage measures temperature as an indicator of circulation (paragraph 54) and neither discloses nor suggests that any *predetermined* temperature is used to limit the duration of treatment.

With respect to claims 4-6, Courtnage neither discloses nor suggests the use of discomfort as a criterion for the continuation or discontinuation of a rapid temperature change. As previously discussed, no rapid temperature change is disclosed or suggested by Courtnage. Although Courtnage discloses thermal sensors and biofeedback loops, Courtnage neither discloses nor suggests any interaction with a subject such as would be required to assess a level of discomfort. Neither discomfort, nor any measure thereof, is disclosed or suggested by Courtnage, and there is no indication that discomfort is a variable in any method disclosed by Courtnage.

With respect to claim 7, Courtnage neither discloses nor suggests that any causing of a rapid temperature change is *repeated based on an assessment of a suspected area for occurrence of infection*. As previously discussed, no rapid temperature change is disclosed or suggested by Courtnage. Also as previously discussed, Courtnage neither

discloses nor suggests that the disclosed thermal or EMG sensors may be used to assess occurrence of infection. Furthermore, although Courtnage uses sense measurements to adjust the therapeutic protocol, such adjustments are made to certain characteristics of therapy, including intensity, waveform, voltage and current (Paragraph 55) and there is no indication that any steps are repeated based on the sense measurements.

Regarding the inherency of either a dialogue with the patient or the repeating of steps (a) – (c) as required by claims 4-7, Applicant notes that Courtnage specifically describes that sensors are used to alter variables during treatment, and further describes specific alterations such as the intensity of waveforms, and voltage, which Courtnage regards as relevant to the system and method disclosed (Paragraph 45 and 55). Accordingly, Applicant fails to discern any indication that any dialogue with a patient or repeating of steps is inherent in Courtnage, as other approaches are specifically disclosed that are in accordance with Courtnage's automated regulatory systems.

In view of the above, Courtnage fails to show or suggest the present invention as recited in independent claim 1. Thus, claim 1 is patentable over Courtnage. Dependent claims 2-7 are allowable for at least the same reasons.

Independent claim 8 recites an apparatus, including a thermal energy source for altering a *surface temperature* of a heat transfer element. Courtnage neither discloses nor suggests a surface temperature of a heat transfer element, nor does Courtnage disclose or suggest a mechanism for altering a surface temperature. Instead, Courtnage discloses a system for altering the *intensity or waveform* of photons *emanating from* an LED (Paragraph 55).

The Examiner suggests that the transparent surface layer 120 equates to a surface of a heat transfer element. Applicant respectfully disagrees with this assertion. There is no indication in Courtnage that the transparent surface layer 120 would in any way conduct heat. In fact, the suggestion by Courtnage that the contact layer comprise silicone (Paragraph 36), which would require special fillers for thermal conductivity, suggests that the surface layer does not function as a thermal conductor, and instead functions to protect, and conduct light transmitted by, the LEDs. Furthermore, Courtnage's discussion of the optical transparency of the protective layer (Paragraph 17) suggests that the primary focus of any such layer is optical transmission of light produced by the LEDs as well as protection of the LEDs from contamination that may result from direct contact with a living organism. With respect to thermal conductivity, only the housing of the Courtnage device is addressed (Paragraph 17). There is no indication that the housing contacts or is in close proximity to any suspected area of infection.

Applicant further notes that the surface layer 120 of Courtnage is described by the Examiner as an "insulating element" in the discussion of claim 14 on p. 3 of the Office Action. The only discussion of insulation in Courtnage relates to the housing (Paragraph 17) and there is no mention of any insulating characteristic of the surface layer 120. Furthermore, even assuming *arguendo* that the contact layer were thermally conductive, there is no evidence to suggest that any alteration in the intensity or waveform of photons emitted by a diode, as described in Paragraph 55 of Courtnage, will result in any change in the *surface temperature* of the contact layer.

In view of the above, Courtnage fails to show or suggest the present invention as recited in independent claim 8. Thus, claim 8 is patentable over Courtnage. Dependent

claims 9-11, 13, 14 and 16 are allowable for at least the same reasons.

Independent claim 18, as amended, recites a method for using an apparatus for inhibiting infection, including a positioning of a surface of a heat transfer element in close proximity to a suspected area of infection, and activating the apparatus such that a rapid temperature change occurs in the suspected area of infection. As previously discussed, a rapid temperature change is believed by the Applicant to inhibit the occurrence and/or spread of an infection and is one advantage of embodiments of the instant invention.

Courtnage, as previously discussed, neither discloses nor suggests a rapid temperature change in a suspected area of infection. Courtnage instead discloses a system and method for facilitating natural physiological processes of a living organism using light therapy and electrotherapy. Courtnage further fails to disclose any surface of a heat transfer element, nor does Courtnage disclose the positioning of any such surface in close proximity to a suspected area of infection.

In view of the above, Courtnage fails to show or suggest the present invention as recited in independent claim 18, as amended. Thus, claim 18 is patentable over Courtnage. Dependent claims 19 - 24 are allowable for at least the same reasons.

In summary, Courtnage fails to disclose or suggest at least the *rapid* temperature change, and the *assessing* as recited in independent claim 1, Courtnage further fails to disclose or suggest the *surface temperature of a heat transfer element* as recited in independent claim 8, and the *rapid* temperature change and positioning of a *surface of a*

heat transfer element, as required by independent claim 18, as amended. For at least these reasons independent claims 1, 8, and 18 are patentable over Courtnage. Dependent claims are patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-10, 13-16, and 18, 19, 21, and 23-24 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,468,295, issued to Augustine et al. (“Augustine”). Claim 18 has been amended in this reply to clarify the present invention recited. To the extent that this rejection may still apply to the amended claims, the rejection is respectfully traversed.

Augustine relates to a wound treatment device for the treatment of skin lesions and other external trauma. The wound treatment device may be configured to accommodate a wound heater over a predetermined wound treatment area formed by the wound treatment device.

Wound heaters such as those disclosed by Augustine are typically used to bring about small temperature changes at the surface of a living organism. Typically, such heating will increase the localized temperature by only a few degrees, and such heaters are sometimes used to raise a skin surface temperature only up to a normal body temperature. Because the temperature of such heaters is very close to that of a normal body temperature, any temperature changes at a wound site will be very gradual. (See, e.g., Patents No. 5,954,680, and 6,407,307, both issued to Augustine)

In contrast to Augustine, the method of claim 1 requires a *rapid* temperature change. No such rapid temperature change is disclosed or suggested by Augustine.

Instead Augustine mounts a planar heater at a distance over a wound defined by a wound treatment volume (Col. 3, l. 30 and Figs. 1 and 11B). Augustine neither discloses nor suggests that either a configuration of the heater, or its distance from a wound surface, would result in a rapid temperature change. Furthermore, a heater according to Augustine would only raise a surface temperature of a target area and there is no disclosure or suggestion of cooling.

Also in contrast with claim 1, Augustine fails to disclose or suggest assessing a suspected area for occurrence of infection after causing and then discontinuing a rapid change in temperature in the suspected area. Augustine also fails to disclose or suggest that a temperature change is continued until a predetermined temperature is reached, as required by claims 2-3, or that discomfort is considered as a factor for continuation or discontinuation of a rapid temperature change. The only reference to discomfort by Augustine is in regard to the comfort of the disclosed device relative to prior art bandages, and its ability to articulate with a joint when attached to a subject. For at least these reasons claim 1, and claims 2-7 which depend therefrom, are patentable over Augustine.

Claim 8 recites an apparatus having a heat transfer element with a surface configured to be in close proximity to a suspected area of infection, and a thermal energy source for altering a temperature of the surface of the heat transfer element until a predetermined temperature is reached. Augustine neither discloses nor suggests that a *surface* of a heat transfer element is *configured* to be in close proximity to a suspected area of infection, nor does Augustine disclose or suggest any mechanism for altering the

temperature of any such surface. Furthermore, the planar heater disclosed by Augustine is located at a set distance from a wound, separated by a wound treatment volume. Such a configuration will not allow for the positioning of the planar heater in close proximity to a suspected area of infection as required by claim 8. Finally, the Augustine device addresses only surface wounds of a living organism and there is no provision for a positioning of the device proximal to any other suspected area of infection (See Paragraph 33, and Fig. 2 of the instant application). For at least these reasons claim 8, and claims 9-10 and 13-16 which depend therefrom, are patentable over Augustine.

Claim 18, as amended, recites a method for using an apparatus for inhibiting infection, including positioning a surface of a heat transfer element in close proximity to a suspected area of infection, and activating the apparatus such that a *rapid* temperature change occurs in the suspected area of infection. As previously discussed, Augustine neither discloses nor suggests a rapid temperature change in a suspected area of infection. Furthermore, the configurations disclosed by Augustine do not allow for the positioning of a heat transfer element in close proximity to certain suspected areas of infection. For at least these reasons amended claim 18, and claims 19-24 which depend therefrom, are patentable over Augustine. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C § 103

Claim 12 stands rejected under 35 U.S.C. § 103 as being obvious over Cournage. This rejection is respectfully traversed.

Claim 12 recites an apparatus for inhibiting infection, including a heat transfer element having a surface configured to be in close proximity to a suspected area of infection, a thermal energy source for altering a temperature of the surface of the heat transfer element until a predetermined temperature is reached, and a temperature detector which regulates activation of the thermal energy source. As previously discussed, Courtnage fails to disclose or suggest a surface of a heat transfer element disposed in close proximity to a suspected area of infection. Courtnage also fails to disclose or suggest any method for regulating the temperature of any such surface, or any use of a predetermined temperature. Although Courtnage does disclose thermal sensors, such sensors are used only for thermographic recording and comparison (Paragraphs 38 and 44), and as an indicator of circulation and/or muscle contraction (Paragraph 54). Courtnage neither discloses nor suggests the use of such sensors to regulate temperature. For at least these reasons, claim 12 is patentable over Courtnage. Accordingly, withdrawal of this rejection is respectfully requested.

Other Prior Art

U.S. Patent Application No. 2002/0165529 by Danek (“Danek”) was cited by the Examiner as being pertinent to claims 8, 10, 11, and 13-16. Danek discloses various configurations of an apparatus for energy delivery at and just below a tissue surface (Paragraphs 5 and 7). In contrast to the claimed embodiments, Danek fails to disclose or suggest any mechanism for the *inhibition of infection*. Danek further fails to disclose or suggest a heat transfer element having a surface configured to be positioned in close proximity to a *suspected area of infection*. Danek further fails to disclose or suggest a

thermal energy source for altering a temperature of the surface of the heat transfer element until a *predetermined temperature* is reached. For at least these reasons, claim 8 is patentable over Danek. Claims 10, 11, and 13-16, which depend from claim 8, are patentable for at least the same reasons.

U.S. Patent No. 5,411,541, issued to Bell et al. (“Bell”) was cited by the Examiner as being pertinent to claims 8, 10, 11, and 13-16. Bell discloses a portable fluid therapy device. In contrast to claim 8, Bell fails to disclose or suggest a thermal energy source for altering a temperature of a surface of a heat transfer element until a *predetermined temperature* is reached. Bell instead discloses a temperature gauge for simply displaying a temperature of water flowing from an inner chamber to a reservoir (Col. 7, ll. 37-38, 45-46). For at least this reason, claim 8 is patentable over Bell. Claims 10, 11, and 13-16 are patentable for at least the same reasons.

Allowable Subject Matter

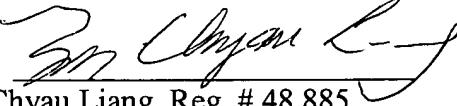
Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. For reasons set forth above, Applicant believes the independent claim from which claim 17 depends is allowable. Therefore, Applicant respectfully defers rewriting claim 17 at this time.

Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account No. 50-0591 (Reference No. 17090.002001).

Respectfully submitted,

Date: May 26, 2005

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